#### UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF WEST VIRGINIA AT CLARKSBURG

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM CORPORATION, and BOEHRINGER INGELHEIM & CO. KG,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC., MYLAN INC., and MYLAN LABORATORIES LIMITED,

Defendants.

C.A. No. 1:20-cv-19 (TSK) (lead)

Consolidated with C.A. No. 1:20-cv-90 (TSK) C.A. No. 1:24-cv-82 (TSK)

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE DEFENDANTS' EXPERT REPORTS AND TESTIMONY CONCERNING THE DISTRICT OF NEW JERSEY ACTION

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#### I. Introduction

Plaintiffs' Motion seeks to exclude purported "legal arguments" by Mylan's experts Dr. William Biggs and Dr. Mukund Chorghade. Mylan's experts, however, do not offer legal arguments or legal conclusions. They do not construe legal opinions, laws, regulations or agreements, nor do they apply legal doctrines to facts to reach ultimate legal conclusions. Instead, the experts simply state certain assumptions about the affirmed-on-appeal decision of the New Jersey court (the "DNJ Action") and point out parallels between their own factual conclusions and those reached by that court. Assumptions are routine in any expert testimony, and they are appropriate grounds for cross-examination. But none of the authorities Plaintiffs cite suggests experts who set forth factual prior-art-based opinions, as Mylan's experts do, are prohibited from pointing to findings in related litigation and noting the agreement with their own. Plaintiffs' position—that references to a relevant decision in a prior action are an attempt to "launder legal arguments through technical experts," Plaintiffs' Brief ("Br.") 3—is an overstatement approaching absurdity.

Notably, Plaintiffs nowhere quote the Federal Circuit decision affirming the New Jersey court. But understanding what that opinion says *on its face* is important, because it fatally undermines Plaintiffs' arguments that Mylan's experts are offering "legal opinions" at all. In affirming the DNJ Action decision, the Federal Circuit held "the district court did not clearly err in determining that a skilled artisan would have a reasonable expectation of arriving at the claimed 2.5 mg and 5 mg dosages through routine experimentation," and there was "no clear error in the

<sup>&</sup>lt;sup>1</sup> The issue-preclusive effect of the findings in the New Jersey court will be settled by this Court in response to Mylan's Motion in Limine No. 2 (Dkt. No. 367). Regardless, Plaintiffs are not entitled to strike all references to related factual findings in an affirmed decision about linagliptin, including the findings supporting the obviousness of the doses at issue here.

district court's secondary consideration analysis." *Boehringer Ingelheim Pharms. Inc. v. Mylan Pharms. Inc.*, 803 F. App'x 397, 402 (Fed. Cir. 2020). These were the Federal Circuit's conclusions. It affirmed factual findings reached by the district court—the use of a "clear error" standard indicates these *were* factual findings. *See id.* at 401 ("[W]e review a district court's . . . findings of fact for clear error."). There was no need to "extract what the[] [experts] call 'findings,'" Br. 10-11; they are stated plainly in the opinion. There was no further appeal. The decision stands. Reiterating what the opinion straightforwardly says with context supplied by counsel, and stating an assumption made with counsel's guidance, is well within the bounds of permissible expert opinion.

It is thus unsurprising that neither expert purported to have "qualifications to interpret court opinions," Br. 2, because neither purported to "interpret court opinions" at all. Nor did they offer opinions on whether those decisions are "legally valid." *Id.*<sup>2</sup> They did not *opine* that the decision was binding on this Court. They stated an *assumption* that certain factual propositions were true. Nothing in the cases Plaintiffs cite supports exclusion of stated assumptions or basic acknowledgements of relevant prior judicial decisions and the language of those decisions. Critiques of assumptions experts make is fodder for cross-examination, not grounds for exclusion. If Plaintiffs believe the reports are misstating those decisions—something they notably *do not argue*—they may address that at trial. Accordingly, the Court should deny Plaintiffs' Motion to exclude outright any testimony making reference to the DNJ Action.

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<sup>&</sup>lt;sup>2</sup> Indeed, there can be no question that the DNJ court's ruling, which was affirmed by the Federal Circuit, is "legally valid."

#### II. Argument

#### A. Experts Are Routinely Permitted to Refer to Law and Make Assumptions.

While "[a]n expert may not state legal conclusions drawn by applying the law to the facts," "an expert may refer to the law in expressing his or her opinion." *United States v. Bedford*, 536 F.3d 1148, 1158 (10th Cir. 2008) (cleaned up). In particular, "the Federal Circuit has expressly discussed the helpfulness of an expert's opinion on the legal conclusion of obviousness 'as relevant to the factual aspects of the analysis leading to that legal conclusion." *Days Corp. v. Lippert Components, Inc.*, No. 3:17CV208-PPS/MGG, 2022 WL 1237433, at \*3 (N.D. Ind. Apr. 27, 2022) (quoting *High Point Design LLC v. Buyers Direct, Inc.*, 730 F.3d 1301, 1313 (Fed. Cir. 2013)). Ordinarily, if "opinion testimony [] embraces an ultimate issue of fact" but does not "state a legal conclusion," it is permissible. *Myers v. Taylor*, No. 14cv156, 2015 WL 12763630, at \*3 (N.D.W. Va. June 24, 2015).

Plaintiffs distort this uncontroversial standard of law to raise objections to fundamentally unobjectionable reports. For example, Plaintiffs cite *United States v. McIver*, 470 F.3d 550 (4th Cir. 2006), for the proposition that "[O]pinion testimony that . . . draws a legal conclusion . . . is generally inadmissible." Br. 9 (quoting *McIver*, 470 F.3d at 562). But Plaintiffs' second set of ellipses elide the actual standard: "[O]pinion testimony that . . . *draws a legal conclusion by applying law to the facts* is generally inadmissible." *McIver*, 470 F.3d at 562 (emphasis added). Plaintiffs presumably omit this language because they cannot articulate what "law"—what doctrine or principle—the experts are purportedly invoking and "applying [] to the facts."

*McIver* demonstrates that Plaintiffs are vastly over-reading the precedents they cite, and the rest of the cases Plaintiffs refer to—none of them remotely resembling this one—confirm it. Consider their flagship authority, *Sparton Corp. v. United States*, 77 Fed. Cl. 1 (2007) (cited at Br. 1). There, the expert—a law professor—offered "testimony to serve the sole purpose of advising

the Court on how to interpret [federal regulations] and the contract provisions and whether to apply [a certain legal] doctrine." *Id.* at 9. "Such legal conclusions [were] the province of the Court." *Id.* Mylan's experts offer nothing of the sort.

The same is true of the rest of Plaintiffs' cases. E.g., United States v. Lupton, 620 F.3d 790, 799 (7th Cir. 2010) (testimony drawing conclusions "about [defendant's] activity . . . based on [the expert's] interpretation of [a] statute"); United States v. Smithers, No. 1:17CR00027, 2025 WL 1527499, at \*4 (W.D. Va. May 29, 2025) (testimony on "whether the defendant was required to follow the law, or that any deviation from the law was ethically permissible because professional health care standards may conflict with the law"); Georges v. Novartis Pharms. Corp., No. CV 06-5207 SJO VBKX, 2012 WL 9064768, at \*9 (C.D. Cal. Nov. 2, 2012) (testimony on "whether Defendant was in regulatory compliance with the FDA"); Sun Yung Lee v. Clarendon, 453 F. App'x 270, 273 (4th Cir. 2011) (testimony "that a valid easement was created in the deed of partial release and that the deed of partial release was within Zom's chain of title"); United States v. Barile, 286 F.3d 749, 761 (4th Cir. 2002) (testimony that "510(k) submissions did not contain 'materially misleading statements"). Again, the statements to which Plaintiffs object here are worlds away from the kinds of "legal conclusions"—applying legal principles or doctrines to facts—that courts exclude. The reason is simple: Plaintiffs are ultimately quarreling with these experts' assumptions of things that "embrace[] . . . issue[s] of fact." Myers, 2015 WL 12763630, at \*3.

Although Plaintiffs acknowledge that Drs. Biggs and Chorghade's statements involve "assumptions," *see* Br. 1, 6, 8, 11, they do not mention the bedrock principle that "experts are allowed to rely on assumptions as part of their opinions," so long as those assumptions are proven at trial. *TQP Dev., LLC v. Merrill Lynch & Co.*, No. 2:08-CV-471-WCB, 2012 WL 3283356, at

\*3 (E.D. Tex. Aug. 10, 2012) (Bryson, J., sitting by designation) (permitting expert opinions that "relied on assumptions presented to [the expert] by . . . counsel"); *Canrig Drilling Tech. Ltd. v. Trinidad Drilling L.P.*, No. CV H-15-0656, 2016 WL 7188657, at \*6 (S.D. Tex. Dec. 12, 2016); *cf. Dorman Prods., Inc. v. Paccar, Inc.*, 201 F. Supp. 3d 663, 690 (E.D. Pa. 2016) ("All damages expert opinions are dependent, for example, on the assumption that liability has been proven."). "An expert's opinions are not inadmissible simply because an underlying assumption may be contestable," *In re Zurn Pex Plumbing Prods. Liab. Litig.*, 644 F.3d 604, 615 (8th Cir. 2011); rather, "complaints about assumptions . . . go to the weight of [the] testimony, rather than its admissibility." *Koenig v. Beekmans*, No. 515CV00822RCLRBF, 2017 WL 6033404, at \*4 (W.D. Tex. Dec. 5, 2017). Applying these principles, there is no basis to exclude this testimony.

# B. Neither Expert Provides a "Legal Opinion"; They Describe Factual Findings and Permissibly Assume the Found Facts Are True.

Straining to transform these experts' reiteration of the text of a decision and assumption of certain facts into a "legal opinion," Plaintiffs argue that Drs. Chorghade and Biggs effectively "[d]etermin[e] what a court found and whether those findings apply to different patents in a different case," which "are legal conclusions." Br. 11. But, as discussed, any assumptions given by counsel are fair game for cross examination; it is not impermissible to "assume," with the guidance of counsel, that certain facts are established. *See, e.g., TQP Dev.*, 2012 WL 3283356, at \*3 (testimony that "simply assumed that some limitations were met" was permissible). And merely stating *that* a court decided something—for example, factual questions resolved in the course of an obviousness analysis—does not "determine" any legal question and thus is not a "legal conclusion." *Cf. Bedford*, 536 F.3d at 1158. A fair reading of the few statements Plaintiffs challenge here shows this is a tempest in a teapot.

Stating Findings and Assumptions. Plaintiffs first challenge a basic statement of assumed facts. Dr. Chorghade—in adopting Dr. Palmieri's report, *see* Br. 1 n.1—states that "the [DNJ] Court has made the following findings that are relevant to [his] invalidity opinions for the Asserted Patents," including that "the use of 2.5 and 5 mg per day of linagliptin to treat type 2 diabetes would have been determined by routine experimentation as of 2006," and "any secondary considerations of non-obviousness were insufficient to overcome the obviousness findings." Br. 7-8 (quoting Ex. 2 at ¶ 32 (adopting Ex. 3 at ¶¶ 69, 70); Ex. 4 at ¶ 13 (adopting Ex. 5 at ¶¶ 44, 45)). Dr. Chorghade "assume[s] that these findings by the District Court (and affirmed by the Federal Circuit) are settled matters of fact." *Id.* at 8 (quoting Ex. 2 at ¶ 32 (adopting Ex. 3 at ¶¶ 70); Ex. 4 at ¶ 13 (adopting Ex. 5 at ¶¶ 45)). Dr. Biggs similarly paraphrases determinations of the district court and the Federal Circuit's affirmation thereof, adding that, "[f]or purposes of this report, I assume that these findings . . . are settled matters of fact." Ex. 1 at ¶¶ 124-126 (quoted at Br. 7).

Plaintiffs object to this testimony because it purportedly "extract[s] what [the experts] call 'findings'" and "declare[s] them binding on this case." Br. 9-10. But it does not "extract" or "declare" anything. They are, in essence, *paraphrasing text* from legal opinions that are straightforwardly written and readily comprehensible. They are not interpreting the opinion, divining a legal rule from it, or arguing a statute or legal doctrine requires a certain result in this case. Moreover, as Plaintiffs point out, "th[eir] understandings came from counsel." Br. 9. The experts merely state several things that they understand were "found" in a prior case and explain that they *assume* that certain *underlying facts* are true. That is, after all, the effect of assuming that factual "findings" are "established." *Cf. TQP Dev.*, 2012 WL 3283356, at \*2. Drs. Biggs and Chorghade are ultimately offering factual opinions, not legal ones. *See Myers*, 2015 WL 12763630, at \*3.

<u>Dr. Biggs's Substantive Analysis.</u> Plaintiffs take issue with two additional statements by Dr. Biggs. Neither statement purports to offer legal analysis or opinion; rather, they refer to the DNJ decision as corroboration.

First, Plaintiffs object to Dr. Biggs's explanation that a POSA "would have determined through routine experimentation that 5 mg of linagliptin was a pharmaceutically effective amount based on *at least* the same prior art and evidence that informed the analysis cited by the New Jersey court." Br. 7 (quoting Ex. 1 at ¶ 263; Ex. 20 at ¶ 234) (emphasis added). But the context, which Plaintiffs omit, makes clear that this is not a bare "legal conclusion" that applies a statute or legal doctrine to the facts. The reference in the Opening Report, for example, appears after Dr. Biggs's substantive analysis of an OTDP reference patent (the '648 patent) with a specification that is *identical* to prior art disclosures cited in the DNJ Action (the Himmelsbach '510 Publication), as well as in this case:

[A] POSA would look to the '648 patent specification to understand what the term "pharmaceutically effective amount" in reference claim 7 meant. The '648 patent specification teaches that the described compounds should preferably be orally administered in an amount from 1-100 mg, one to four times per day. See '648 patent at col. 19, ll. 16-19. This is identical to the dosage described in the Himmelsbach '510 Publication that courts previously found made using 5 mg of linagliptin to treat type diabetes obvious to a POSA in 2006, well before the priority date of the '526 patent. . . . Thus, a POSA in August 2008 would have determined through routine experimentation that 5 mg of linagliptin was a pharmaceutically effective amount based on at least the same prior art and evidence that informed the analysis cited by the New Jersey court.

Ex. 1 at ¶ 263; see Ex. 20 at ¶ 232 (assessing substance of '510 publication before discussing prior findings). This is not a conclusory legal opinion. It expresses Dr. Biggs's opinion about what a POSA would understand from the '648 patent and could, in August 2008, determine by routine experimentation, making reference to his permissible assumption that the findings of the DNJ

Action concerning the Himmelsbach '510 publication are "established." Indeed, the '648 patent "shares the same specification as the Himmelsbach '510 publication," Ex. 1 at ¶ 263 n. 36, and Dr. Biggs subsequently provides a substantive analysis of the '510 publication, *see id.* at ¶ 265 (beginning of analysis). Citing corroborative sources, even if not relied upon as "prior art," is not articulating a "legal opinion."

Second, Plaintiffs challenge Dr. Biggs's recitation of his understanding that, with respect to the '859 patent, the DNJ court "previously determined that, as of 2006, 'the metformin dosages, and that metformin could be combined with DPP-IV inhibitors like linagliptin, were disclosed in the prior art." Br. 7 (quoting Ex. 1 at ¶¶ 331). Plaintiffs take issue with his "agree[ment]" with the substantive determination that "methods of treating type 2 diabetes by administering linagliptin and metformin would have been obvious, at least by 2006" because he points out that the same determination holds for "the '379 patent." Br. 7 (quoting *id.* at ¶ 332). (Indeed, he states that opinion independently of any prior litigation. *See* Ex. 1 at ¶ 329.) There is nothing improper about *assuming* certain facts are established, *see id.* ¶¶ 124-126, and then pointing out that his (permissible) opinion on obviousness based on underlying facts, *see High Point Design*, 730 F.3d at 1313, accords with a decision that has already been reached based on overlapping facts. Ex. 6 at 125:20-22.

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<sup>&</sup>lt;sup>3</sup> Because Plaintiffs challenge only the last sentence of this paragraph, there is no dispute that Dr. Biggs may permissibly testify that the dosages in these two documents are "identical." Nor is there any dispute that Dr. Biggs may testify that the dosages described in the '648 patent would lead a POSA to the conclusion that 5mg of linagliptin was a pharmaceutically effective amount by routine experimentation—the same underlying substantive finding made by the court in the DNJ Action with respect to the '510 publication.

# C. Plaintiffs' Objections, Based on the False Premise That These Are "Legal Opinions," Are Meritless.

Based on their incorrect premise that Drs. Biggs and Chorghade offer "legal conclusions," Plaintiffs further contend that the testimony at issue is not based on "expertise" and that it is neither "reliable" nor "relevant." Br. 12-16. The first two objections are misguided; the third is wrong.

First, Plaintiffs argue the experts' restatements of straightforward propositions appearing in legal opinions must be excluded because neither of them is an "expert[] in 'reviewing court opinions' or "'distinguishing between legal findings and fact findings," Br. 11-12 (quoting Ex. 6 at 18:17–19:1; Ex. 7 at 19:2–7), and because their "methodology" is "unreliable," Br. 12-14. To begin with, Plaintiffs cite no authority to suggest that "legal expertise" is required for an expert to review legal opinions and note what they say. Opinions are documents embodying, among other things, findings of fact, and there is no dispute that the Federal Circuit found no "clear error" in any of the "findings" that the experts recite.

More fundamentally, though, the "expertise" and "methodology" objections do not square with what Drs. Biggs and Chorghade are actually doing. They are not rendering a legal opinion; they are reproducing a set of propositions and stating their assumption that those propositions are true. *See* Ex. 6 at 124:19-125:1 (Dr. Biggs confirming he was merely "reciting the Federal Circuit's opinion but . . . not providing an independent opinion relating to the Federal Circuit's order" and making clear that, as to the DNJ Action findings, he is just "assuming that the findings of obviousness of the use of a 5-milligram per day linagliptin to treat type 2 diabetes has already been adjudicated by the court and has been settled"). Neither expertise nor methodology is required to "recite[]" and "assum[e]" facts stated in a court decision concerning pharmaceutical subject matter that *is* within an expert's uncontested area of expertise.

Finally, Plaintiffs object that the statements at issue are not "relevant to any issue in this case." Br. 14. (They later impose a different standard, arguing that the statements are not "relevan[t] to Dr. Biggs'[s] and Chorghade's *validity opinions*." Br. 16 (emphasis added).) As a matter of common sense, it is difficult to imagine how facts found in a prior decision regarding patents involving the same substance, factual underpinnings, and overlapping prior art are flatly "irrelevant" to this case. Plaintiffs, however, take the position that statements about the DNJ Action are *per se* irrelevant and must be excluded because Dr. Biggs, for example, testified that factual findings from the previous decision are not a "basis for" his obviousness opinion. See Br. 14-16 (quoting Ex. 6 at 125:11-126:1) (emphasis added). Plaintiffs argue that this "contradict[s] his reports," Br. 14, and represents a "disavow[al] of any opinion" that the findings are relevant at all, id. at 15. But Dr. Biggs never testified that the findings in the DNJ Action decisions were irrelevant, and it is not clear how they construe his testimony to "disavow" any relevance at all.

To the contrary, Dr. Biggs pointed out that both this case and the previous one involve the "same compound," Ex. 6 at 118:19, adding that the DNJ Action decisions were based on some of the "same material" and "some of the same underlying facts," *id.* at 125:21-22. And while none of his opinions *rely on* those factual findings, they are certainly *bolstered* by them. For example, by opining that a POSA would have reached a certain conclusion "through routine experimentation . . . based on *at least* the same prior art and evidence that informed the analysis cited by the New Jersey court," Ex. 1 at ¶ 263 (emphasis added), Dr. Biggs was pointing out that the '648 patent specification renders a certain therapeutically effective dose obvious *in the same way* as the Himmelsbach '510 publication was previously found to render that dose obvious. Assuming (as Dr. Biggs does) that the underlying factual findings *are* to be established for purposes of this case, they provide powerful corroboration.

#### III. Conclusion

Plaintiffs' Motion seeks the extreme remedy of exclusion for a small set of straightforward statements: recitations of what a court previously concluded in a case about linagliptin; assumptions that the underlying factual findings were "established," *i.e.*, accurate; and observations about what implications such facts have for a substantive opinion on obviousness. None of this amounts to a forbidden "legal conclusion." All of it can be tested on cross-examination. The Court should deny Plaintiffs' Motion.

Respectfully submitted,

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Dated: August 8, 2025

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### **CERTIFICATION OF SERVICE**

I hereby certify that on this, the 8th day of August 2025, I filed the foregoing "Memorandum in Opposition to Plaintiffs' Motion to Exclude Defendants' Expert Reports and Testimony Concerning the District of New Jersey Action" using the Court's CM/ECF system, which will send notification of the same to all counsel of record in this matter.

/s/ William J. O'Brien

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